

REMARKS

Claim Rejections – 35 USC §103

Claims 1, 2, 4, 7, 8, 10-18, 21 and 31-44 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,136,003 to Van Hoeek et al. in view of U.S. Patent No. 3,399,433 to Faulkner, and claims 3 and 5 have been rejected in further view of U.S. Patent No. 6,238,396 to Lombardo.

Claim Amendments

Independent claims 1, 13 and 33 have been amended to recite the subject matter of dependent claims 40, 42 and 44, respectively, and dependent claims 40, 42 and 44 have been cancelled without prejudice for possible submission in a continuing application.

Arguments in Support of Patentability

The seminal case directed to the application of 35 U.S.C. §103 is Graham v. John Deere, 148 USPQ 459 (1966). From this case, four familiar factual inquiries have resulted. The first three, determining the scope and content of the prior art, ascertaining differences between the prior art and the claims at issue and resolving the level of ordinary skill in the pertinent art, are directed to the evaluation of prior art relative to the claims of the pending application. The fourth factual inquiry is directed to evaluating evidence of secondary considerations. (See, *Manual of Patent Examining Procedure* (MPEP) §2141). While performing this analysis, the cited references must be considered in their entirety, i.e., as a whole, including portions that would lead away from the claimed invention. (See, MPEP §2141.02 (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983))). From these inquiries, the initial burden is on the Examiner to establish a *prima facie* case of obviousness.

Additionally, the Supreme Court in the recent decision of KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 127 S.Ct 1727, 167 L.Ed.2d 705 (U.S. 2007), citing In Re Kahn, 441 F.3d 977, 988 (CA Fed. 2006), stated:

[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

KSR, 82 USPQ2d at 1396. For at least the following reasons, it is respectfully submitted that the pending claims are patentable over the cited references.

Faulkner Constitutes Nonanalogous Art

As indicated above, Graham initially requires that the scope and content of the prior art be determined. Pursuant to the obligation to determine the appropriate scope and content of prior art, the Manual of Patent Examining Procedure requires that “[t]he examiner must determine what is ‘analogous prior art’ for the purpose of analyzing the obviousness of the subject matter at issue”, and that “[i]n order to rely on a reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.” MPEP §2141.01(a); citing In re Oetiker, USPQ.2d 1443, 1445 (Fed. Cir. 1992).

The Applicant respectfully submits that Faulkner is clearly not analogous art to Van Hoeck or to the invention recited in the pending claims. Specifically, Faulkner discloses a clip for forming a noose in a flexible cable. However, Van Hoeck discloses devices for linking rigid spinal rods in a spinal stabilization system, and the claimed invention is similarly directed to a cross link connector for connecting rigid spinal rods in a spinal stabilization systems, devices which the Applicant submits are in no way analogous or in any way related to the noose cable clip of Faulkner. Although this observation should be evident on its face, the Applicant provides the following detailed analysis in support of this position.

As indicated above, “[i]n order to rely on a reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.” MPEP §2141.01(a). The Applicant submits that a cable clip for forming a noose in a flexible cable is clearly not in the same field of endeavor as a spinal stabilization system. As should be apparent, a cable clip for forming a noose in a flexible cable clearly fall outside of the field of orthopedic spinal stabilization systems that interconnect/link a pair of rigid spinal rods. The Applicant further submits that a clip for forming a noose in a flexible cable is not reasonably pertinent to the particular problems concerning the interconnection/linking of a pair of rigid spinal rods. Indeed, a person of ordinary skill in the art faced with the task of designing an orthopedic spinal stabilization system for interconnecting/linking a pair of rigid spinal rods would not look to the field of noose cable clips to provide direction in the design of a connector/device for interconnecting/linking rigid spinal rods.

Nevertheless, the Office Action asserts that “Faulkner is concerned with providing a clip that is capable of receiving an elongate member. The rigidity of the elongate member is not a factor in the design of the clip itself.” (See page 5, lines 19-21; emphasis added). The Applicant respectfully disagrees. Indeed, the noose cable clip 1 of Faulkner is specifically designed for use in association with a flexible cable 5 to form a noose or loop in the cable that wraps about and supports a load 8. (See Figure 6). An end portion of the flexible cable 5 is engaged by the clip 1 via a stopper 4, an intermediate portion of the flexible cable 5 is wrapped back toward the clip to form a noose or loop (which extends about the load 8), and the opposite end portion of the flexible cable 5 is threaded through the under-cut groove 6 in the clip 1 which bites into the flexible cable to lock the noose. As should be apparent, the cable clip 1 of Faulkner is designed to accommodate and bite into a looped flexible cable to form a noose, and was clearly designed for use in association with a flexible cable as a primary consideration (i.e., a flexible cable is needed to form the looped noose). The Applicant notes that a rigid rod does not have the requisite flexibility to form a loop or noose, and the Faulkner cable clip would therefore not be used in association with a rigid rod. Additionally, in order for the flexible cable 5 to “bite into the undercut parts of the groove 5” (see column 2, lines 14-15 of Faulkner), the cable 5 must have a requisite degree of flexibility. Contrary to the assertion set forth in the Office Action that “the rigidity of the elongate member is not a factor in the design of the clip itself”, the Applicant submits that the cable clip of Faulkner is specifically designed for use in association with a flexible cable which is capable of being formed into a looped noose.

Moreover, the noose cable clip of Faulkner functions significantly different from and serves a much different purpose compared to the rod linking device of Van Hoeck. As an initial matter, the Faulkner cable clip is used in association with a flexible cable to hold the flexible cable in a looped noose, whereas Van Hoeck is directed to a linking device for interconnecting a pair of rigid spinal rods to form a spinal stabilization system. The Applicant submits that the field of noose cable clips (the field of Faulkner) does not constitute analogous or similar art to the field of orthopedic spinal stabilization systems, and the design consideration associated with a noose cable clip are significantly different compared to those associated with interconnecting a pair of rigid spinal rods in an orthopedic spinal stabilization system.

Furthermore, the Federal Circuit has held that the standard for considering whether a reference is reasonably pertinent to the particular problem of a claimed invention as follows:

A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. Thus, the purpose of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it. *In re Clay*, 23 USPQ.2d 1058, 1061 (Fed. Cir. 1992).

Notably, Faulkner does not deal with any problem having a logical connection or relevance to orthopedic spinal stabilization systems including a linking/connector device for interconnecting a pair of rigid spinal rods. Instead, Faulkner addresses problems associated with forming a looped noose in a flexible cable. Accordingly, the teachings of Faulkner would not have logically commended to an inventor's attention in considering the design of an orthopedic spinal stabilization system including a linking/connector device to interconnect/link a pair of rigid spinal rods. Moreover, the teachings of Faulkner are not reasonably pertinent to the design issues and concerns pertaining to orthopedic spinal stabilization systems including the interconnection of a pair of rigid spinal rods, and are directed to an entirely different purpose compared to the orthopedic spinal stabilization system of Van Hoesck. Indeed, the Applicant submits that the concept of providing a cable clip for forming a noose in a flexible cable involves a purpose and function that are clearly different and unrelated to those associated with interconnecting a pair of rigid spinal rods in an orthopedic stabilization system. As a result, one of ordinary skill in the art would not logically look to the field of noose cable clips (i.e., the field of Faulkner) when designing a spinal stabilization system (i.e., the subject matter of Van Hoesck).

For at least these reasons, the claim rejections based on the Van Hoesck/ Faulkner combination are improper since Faulkner constitutes nonanalogous art to Van Hoesck, and one of ordinary skill in the art would combine the teachings of Faulkner (which is specifically directed to a noose cable clip) with the orthopedic spinal stabilization system disclosed in Van Hoesck to arrive at the invention recited in the pending claims of the subject application.

Independent Claim 1 and Dependent Claims 2-5, 7-8, 10-12, 31, 34, 35 and 39

Independent claim 1 stands rejected as being unpatentable over the Van Hoeck/Faulkner combination. As indicated above, independent claim 1 has been amended to include the subject matter of dependent claim 40 and now recites, among other elements and features, “a second hook . . . comprising a second internal surface having a curved portion including a raised ridge extending along said curved portion in a direction from the first end to the second end, wherein said second rod contacts said ridge”, and “wherein said shaft includes a second threaded hole associated with said second hook, and a set screw extends through said second threaded hole contacting said second rod and forcing said second rod against said ridge wherein said second rod is compressed against a crest of said raised ridge”.

The Office Action asserts that Van Hoeck discloses several of the features recited in independent claim 1, but admits that Van Hoeck “does not disclose including a ridge extending along a curved portion in a direction from the first end to the second end”. (See page 3, lines 3-4). However, the Office Action asserts that Faulkner discloses this feature and that “[i]t would have been obvious . . . to modify the device of Van Hoeck et al. (sic) with a ridge extending along the curved portion . . . in order to allow the hook to be wide enough to allow for the rod to be inserted into the hook.” (See page 4, lines 1-4). The Applicant respectfully disagrees.

Van Hoeck discloses a connector 20 that includes a pair of oppositely positioned engaging portions 25, 26, each of which includes a receptacle 36 and a fixation surface 33. (See Figs. 3-5). Faulkner discloses a cable clip for forming a noose in a flexible cable 5 which includes a block 1 including an open sided groove 2 for receipt of an end portion of the flexible cable 5, and an open-sided and under-cut groove 6 for receipt of an intermediate portion of the flexible cable 5 wherein the undercut portion of the groove 6 at the end of the block 1 bites into the cable 5 to hold the flexible cable 5 in a looped or noose configuration. (See Fig. 6).

As set forth in detail above, the rejection of independent claim 1 based on the Van Hoeck/ Faulkner combination is improper since the noose cable clip of Faulkner constitutes nonanalogous art to the spinal stabilization system of Van Hoeck. However, other reasons support the patentability of independent claim 1. For example, independent claim 1 recites that “said second rod contacts said ridge”, and a set screw forces “said second rod against said ridge wherein said second rod is compressed against a crest of said raised ridge”.

As indicated above, the Office Action admits that Van Hoeck fails to disclose “a ridge extending along the curved portion in a direction from the first end to the second end” with the one of the spinal rods in contact against the ridge, but nevertheless asserts that Faulkner discloses these claimed features. The Applicant respectfully disagrees with this assertion. As indicated above, Faulkner discloses a cable clip for forming a noose in a cable with the clip block 1 including an open-sided and under-cut groove 6 for receipt of an intermediate portion of the flexible cable 5 wherein the undercut portion of the groove 6 at the end of the block 1 bites into the cable 5 to hold the flexible cable 5 in a noose or looped configuration. (See Figure 6). However, as illustrated in Figure 6 of Faulkner, even assuming *arguendo* that the flexible cable 5 could somehow be construed as a rod and the undercut groove 6 could somehow be construed to define a raised ridge (positions which the Applicant respectively traverse), the flexible cable 5 is not positioned “in contact against said ridge” and the flexible cable 5 is not forced “against said ridge” and “compressed against a crest of said raised ridge”, as recited in independent claim 1.

Even assuming *arguendo* that the under-cut groove 6 of the noose cable clip 1 of Faulkner could be construed as defining “a ridge”, as clearly illustrated in Figure 6, the flexible cable 5 is not “compressed against a crest of said raised ridge”. As should be appreciated and as pointed out in the Applicant’s previous response, the crest of a ridge constitutes the maximal point or line formed by the meeting of two sloping surfaces. With regard to the cable clip 1 of Faulkner, assuming *arguendo* that the cable clip 1 could be construed as defining a crest or ridge, as illustrated most clearly in Figure 4, the maximal point along the curved surface defined by the left side of the under-cut groove 6 (the point defining the narrowest width along the length of the groove 6) would constitute the crest of such a ridge. However, as illustrated in Figure 6, the flexible cable 5 is not forced into contact with the crest or maximal point along the groove 6. Indeed, the flexible cable 5 does not in any way contact the crest or maximal point of the inner surface defining the under-cut groove 6, but is instead bitten into by the undercut region of the under-cut groove 6 (i.e., the lower end of the under-cut groove 6).

Moreover, the Applicant is cognizant of the assertion set forth in the final Office Action that “the length of figure 4 is the ridge and the rod of Faulkner is shown located as close to the crest as applicants own figures show”. (See page 6, lines 20-22). Additionally, the Office Action refers to the current application and asserts that “[i]n Figure 28 the rod is not located on the apex

of the ridge . . . but appears similar to figure 6 of Faulkner”. (See page 6, lines 9-10). Once again, the Applicant respectfully disagrees with these assertions.

First, the statement in the Office Action that “the rod is not located on the apex of the ridge . . . but appears similar to figure 6 of Faulkner” appears to constitute an implicit admission that the flexible cable 5 of Faulkner is not located at the apex/crest defined by the under-cut groove 6 in the cable clip 1, and is not compressed into contact with the apex/crest defined by the under-cut groove 6. Moreover, the Office Action’s reference to Figure 28 of the current application and the corresponding assertion that “the rod is not located on the apex of the ridge” is also misplaced. Indeed, Figure 28 clearly illustrates that the rigid spinal rod 367 is positioned immediately adjacent and in contact with the crest/apex of the ridge 368 formed by the inclined interior surfaces 362. This feature is what allows the rigid spinal rod 367 to be positioned at variable angular orientations relative to the rigid spinal rod 369 and relative to the connector. Accordingly, Faulkner fails to satisfy the admitted deficiencies of Van Hoeck. Since the subject matter of independent claim 1, as a whole, has not been accounted for by the Van Hoeck/Faulkner combination, a *prima facie* case of obviousness has not been established.

For at least the reasons set forth above, independent claim 1 is submitted to be patentable over the Van Hoeck/Faulkner combination, and withdrawal of the rejection of independent claim 1 and allowance of the same is respectfully requested.

Claims 2-5, 7-8, 10-12, 31, 34, 35 and 39 depend from independent base claim 1 or an intervening claim, and are submitted to be patentable over the cited references for at least the reasons supporting the patentability of independent base claim 1, although further reasons support the patentability of these claims.

For example, claim 39 recites that “said first and second spinal rods comprise rigid rods that are interconnected to provide a rigid interconnection assembly”. However, as indicated above, the cable clip 1 of Faulkner is used to form a looped noose in a flexible cable 5, and does not in any way relate to the interconnection of rigid rods to form a rigid interconnection assembly. Accordingly, one of ordinary skill in the art would not use the cable clip 1 of Faulkner to interconnect a pair of rigid support rods, for to do so would be directly contrary to the teachings of Faulkner.

Independent Claim 13 and Dependent Claims 14-18, 21, 32, 36 and 41

Independent claim 13 stands rejected as being unpatentable over the Van Hoeck/Faulkner combination. As indicated above, independent claim 13 has been amended to include the subject matter of dependent claim 42 and now recites, among other elements and features, “a second hook . . . comprising a second internal surface wherein the second internal surface curves both in a first direction from the shaft to the second end and in a second direction oblique to the first direction, wherein said curves in said first and second directions are overlapping and intersecting to thereby define a raised ridge extending from the first end to the second end, wherein the second spinal rod is locked in contact with said raised ridge and wherein said second rod is compressed against a crest of said raised ridge”

As an initial matter, as set forth in detail above, the rejection of independent claim 13 based on the Van Hoeck/ Faulkner combination is improper since the noose cable clip of Faulkner constitutes nonanalogous art to the spinal stabilization system of Van Hoeck. Additionally, further reasons support the patentability of independent claim 13 similar to those set forth above in support of the patentability of independent claim 1. Accordingly, independent claim 13 is submitted to be patentable over the Van Hoeck/Faulkner combination, and withdrawal of the rejection of independent claim 13 and allowance of the same is respectfully requested.

Claims 14-18, 21, 32, 36 and 41 depend from independent base claim 13 or an intervening claim and is submitted to be patentable over the cited references for at least the reasons supporting the patentability of independent base claim 13, although further reasons support the patentability of these claims.

For example, claim 41 recites that “said first and second spinal rods comprise rigid rods that are interconnected to provide a rigid interconnection assembly”. However, as indicated above, the cable clip 1 of Faulkner is used to form a looped noose in a flexible cable 5, and does not in any way relate to the interconnection of rigid rods to form a rigid interconnection assembly. Accordingly, one of ordinary skill in the art would not use the cable clip 1 of Faulkner to interconnect a pair of rigid support rods, for to do so would be directly contrary to the teachings of Faulkner.

Independent Claim 33 and Dependent Claims 37, 38 and 43

Independent claim 33 stands rejected as being unpatentable over the Van Hoeck/Faulkner combination. As indicated above, independent claim 33 has been amended to include the subject matter of dependent claim 44 and now recites, among other elements and features, “a second hook portion . . . comprising a second internal surface having a curved portion including a saddle defining a raised ridge extending along said curved portion in a direction from said first end to said second end”, and “said second elongated support rod is locked in contact with said raised ridge of said saddle and wherein said second elongated support rod is compressed against a crest of said raised ridge”

As an initial matter, as set forth in detail above, the rejection of independent claim 33 based on the Van Hoeck/ Faulkner combination is improper since the noose cable clip of Faulkner constitutes nonanalogous art to the spinal stabilization system of Van Hoeck. Additionally, further reasons support the patentability of independent claim 33 similar to those set forth above in support of the patentability of independent claim 1. Accordingly, independent claim 33 is submitted to be patentable over the Van Hocck/Faulkner combination, and withdrawal of the rejection of independent claim 33 and allowance of the same is respectfully requested.

Claims 37, 38 and 43 depend from independent base claim 33 or an intervening claim and is submitted to be patentable over the cited references for at least the reasons supporting the patentability of independent base claim 33, although further reasons support the patentability of these claims.

For example, claim 43 recites that “said first and second elongate support rods comprise rigid rods that are interconnected to provide a rigid interconnection assembly”. However, as indicated above, the cable clip 1 of Faulkner is used to form a looped noose in a flexible cable 5, and does not in any way relate to the interconnection of rigid rods to form a rigid interconnection assembly. Accordingly, one of ordinary skill in the art would not use the cable clip 1 of Faulkner to interconnect a pair of rigid support rods, for to do so would be directly contrary to the teachings of Faulkner.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the subject application is in condition for allowance including pending claims 1-5, 7, 8, 10-18, 21, 31-39, 41 and 43.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,



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